changed their vote from ''yea'' to ''nay.''

So the resolution was agreed to.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

□ 1345

## ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, the Chair will postpone further proceedings today on motions to suspend the rules on which a recorded vote or the yeas and nays are ordered, or on which the vote incurs objection under clause 6 of rule XX.

Record votes on postponed questions will be taken later.

## DRUG QUALITY AND SECURITY ACT

Mr. UPTON. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 3204) to amend the Federal Food, Drug, and Cosmetic Act with respect to human drug compounding and drug supply chain security, and for other purposes.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 3204

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Drug Quality and Security Act''.

**SEC. 2. REFERENCES IN ACT; TABLE OF CONTENTS.**

(a) REFERENCES IN ACT.—Except as otherwise specified, amendments made by this Act to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:



## TITLE I—DRUG COMPOUNDING

**SEC. 101. SHORT TITLE.**

This Act may be cited as the ''Compounding Quality Act''.

**SEC. 102. VOLUNTARY OUTSOURCING FACILITIES.**

(a) IN GENERAL.—Subchapter A of chapter V (21 U.S.C. 351 et seq.) is amended—

(1) by redesignating section 503B as section 503C; and

(2) by inserting after section 503A the following new section:

**''SEC. 503B. OUTSOURCING FACILITIES.**

''(a) IN GENERAL.—Sections 502(f)(1), 505, and 582 shall not apply to a drug compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility if each of the following conditions is met:

''(1) REGISTRATION AND REPORTING.—The drug is compounded in an outsourcing facility that is in compliance with the requirements of subsection (b).

''(2) BULK DRUG SUBSTANCES.—The drug is compounded in an outsourcing facility that does not compound using bulk drug substances (as defined in section 207.3(a)(4) of title 21, Code of Federal Regulations (or any successor regulation)), unless—

''(A)(i) the bulk drug substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need, by—

''(I) publishing a notice in the Federal Register proposing bulk drug substances to be included on the list, including the rationale for such proposal;

''(II) providing a period of not less than 60 calendar days for comment on the notice; and

''(III) publishing a notice in the Federal Register designating bulk drug substances for inclusion on the list; or

''(ii) the drug compounded from such bulk drug substance appears on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing;

''(B) if an applicable monograph exists under the United States Pharmacopeia, the National Formulary, or another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph, the bulk drug substances each comply with the monograph;

''(C) the bulk drug substances are each manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

''(D) the bulk drug substances are each accompanied by a valid certificate of analysis.

''(3) INGREDIENTS (OTHER THAN BULK DRUG SUBSTANCES).—If any ingredients (other than bulk drug substances) are used in compounding the drug, such ingredients comply with the standards of the applicable United States Pharmacopeia or National Formulary monograph, if such monograph exists, or of another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph if any.

''(4) DRUGS WITHDRAWN OR REMOVED BECAUSE UNSAFE OR NOT EFFECTIVE.—The drug does not appear on a list published by the Secretary of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective.

''(5) ESSENTIALLY A COPY OF AN APPROVED DRUG.—The drug is not essentially a copy of one or more approved drugs.

''(6) DRUGS PRESENTING DEMONSTRABLE DIFFICULTIES FOR COMPOUNDING.—The drug—

''(A) is not identified (directly or as part of a category of drugs) on a list published by the Secretary, through the process described in subsection (c), of drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients; or

''(B) is compounded in accordance with all applicable conditions identified on the list described in subparagraph (A) as conditions that are necessary to prevent the drug or category of drugs from presenting the demonstrable difficulties described in subparagraph (A).

''(7) ELEMENTS TO ASSURE SAFE USE.—In the case of a drug that is compounded from a drug that is the subject of a risk evaluation and mitigation strategy approved with elements to assure safe use pursuant to section 505–1, or from a bulk drug substance that is a component of such drug, the outsourcing facility demonstrates to the Secretary prior to beginning compounding that such facility will utilize controls comparable to the controls applicable under the relevant risk evaluation and mitigation strategy.

''(8) PROHIBITION ON WHOLESALING.—The drug will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug. This paragraph does not prohibit administration of a drug in a health care setting or dispensing a drug pursuant to a prescription executed in accordance with section 503(b)(1).

''(9) FEES.—The drug is compounded in an outsourcing facility that has paid all fees owed by such facility pursuant to section 744K.

''(10) LABELING OF DRUGS.—

''(A) LABEL.—The label of the drug includes—

''(i) the statement 'This is a compounded drug.' or a reasonable comparable alternative statement (as specified by the Secretary) that prominently identifies the drug as a compounded drug;

''(ii) the name, address, and phone number of the applicable outsourcing facility; and

''(iii) with respect to the drug—

''(I) the lot or batch number;

''(II) the established name of the drug;

''(III) the dosage form and strength;

''(IV) the statement of quantity or volume, as appropriate;

''(V) the date that the drug was compounded;

''(VI) the expiration date;

''(VII) storage and handling instructions;

''(VIII) the National Drug Code number, if available;

''(IX) the statement 'Not for resale', and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement 'Office Use Only'; and

''(X) subject to subparagraph (B)(i), a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

''(B) CONTAINER.—The container from which the individual units of the drug are removed for dispensing or for administration (such as a plastic bag containing individual product syringes) shall include—

''(i) the information described under subparagraph (A)(iii)(X), if there is not space on the label for such information;

''(ii) the following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1–800–FDA–1088 (or any successor Internet Web site or phone number); and

''(iii) directions for use, including, as appropriate, dosage and administration.

''(C) ADDITIONAL INFORMATION.—The label and labeling of the drug shall include any other information as determined necessary and specified in regulations promulgated by the Secretary.

''(11) OUTSOURCING FACILITY REQUIREMENT.—The drug is compounded in an outsourcing facility in which the compounding of drugs occurs only in accordance with this section.